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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,211	12/08/2005	Wridzer Jan Willem Bakker	2003.817US	1246

67706 7590 08/19/2010

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EXAMINER

KASSA, TIGABU

ART UNIT	PAPER NUMBER
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1619

NOTIFICATION DATE	DELIVERY MODE
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08/19/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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patents@spcorp.com

Office Action Summary	Application No. 10/553,211	Applicant(s) BAKKER ET AL.	
	Examiner TIGABU KASSA	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07/06/10.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 17-20 is/are pending in the application.
- 4a) Of the above claim(s) 13-15 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 18-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 October 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07/21/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Formal Matters***

Applicants' amendment filed 07/06/2010 is acknowledged and entered. **Claims 1-15 and 17-20 are currently pending. Claims 1-12 and 18-20 are under consideration in the instant office action.** Claims 13-15 and 17 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claims. Claim 16 is cancelled. This Office Action is FINAL.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 07/21/10 is noted and the submissions are in compliance with the provisions of 37 CFR 1.97. The document DE 3818453 is lined through because it is not in the English language. A copy of the English translated document or an equivalent patent document which is in English language is requested. A signed copy is attached.

Rejections Maintained***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were

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made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness

Claims 1-3, 5-8, 10, 18 and 20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Jakupovic et al. (US Patent No. 6,221,398, IDS reference) in view of Subramaniam et al. (US Patent No. 6,113,795), for the reasons of record and the reasons set forth herein.

Response to arguments

Applicants' arguments filed on 07/06/2010 have been fully considered but they are not persuasive.

Applicants argue that in contrast to a batch process, the instantly claimed process can be easily scaled up for commercial production while maintaining robust control of the particle size (see, e.g., paragraph [151) by allowing for the ratio of solvent to antisolvent to be controlled thereby resulting in more uniform particle size (see, e.g paragraphs [15] and [55t) and avoiding uncontrolled precipitation of solids and the

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formation of agglomerated particles (see, e.g., paragraphs [1511, [20l). In a batch process, such as Jakupovic et al, the ratio of solvent to antisolvent varies and accordingly, so will the particle size. In addition, Jakupovic et al. do not teach or suggest that Pyrex Glass Filters can be easily exchanged for a membrane. Jakupovic et al. do not teach a membrane having 3 μm pore size and shaped as tubes, fibres, and spiral wounds. Accordingly, Jakupovic et al. does not render the claimed invention obvious.

This is not found persuasive because applicants' resorted to attacking the references individually while the rejection is based on the combined teachings of Jakupovic et al. and Subramaniam et al. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The examiner also reminds applicants that a *prima facie* case of obviousness exists for taking a given batch process to a continuous process *In re Dilnot*, 319 F.2d 188, 138 USPQ 248 (CCPA 1963) (Claim directed to a method of producing a cementitious structure wherein a stable air foam is introduced into a slurry of cementitious material differed from the prior art only in requiring the addition of the foam to be continuous. The court held the claimed continuous operation would have been obvious in light of the batch process of the prior art.). Therefore, it is *prima facie* obvious to go from the batch process of Jakupovic et al. to a continuous process. With regard to the membrane having up to 3 μm pore size as it is clearly indicated in the previous office action that Jakupovic et al. do not teach the membrane having up to 3 μm pore size and the shape of the membrane being tubes, fibres, and spiral wounds. However, all these

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deficiencies are clearly cured by the teachings of Subramaniam et al. as also set forth in the previous rejection.

Applicants argue that the membrane of Subramaniam et al. is not used as a precision dosing device but as a means of separating particles from the solvent and antisolvent. Accordingly, Subramaniam et al. does not teach or suggest the use of a membrane as a precision dosing device. The use of a membrane as a precision dosing device is taught only in the present invention. Accordingly, Subramaniam et al. does not remedy the deficiencies of Jakupovic et al.

This is not found persuasive because applicants' resorted to attacking the references individually while the rejection is based on the combined teachings of Jakupovic et al. and Subramaniam et al. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). For Subramaniam et al. to be a proper prior art they do not have to teach the drug particles passed through the membranes because this limitation is clearly addressed by the teachings of the Jakupovic et al. Jakupovic et al. teach that once the compound is dissolved the solution is preferably added to the antisolvent through **a porous filter** having pores of 10-160 microns (column 4, lines 24-27). This teaching reads on the limitation reciting forcing the liquid medium through a membrane. The skilled artisan would have been motivated to use a membrane having up to 3 μm pore size and the shape of the membrane is selected from tubes, fibres, and spiral wounds in such a process, because Subramaniam et al. teach that those skilled in the art will

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appreciate that the average pore size can be adjusted to suit the particular application (column 3, lines 49-51). For example, the membranes can be selected for retaining particles having the following desired particle sizes: particles having an average size of less than about 0.5 μm for use in forming cancer treating agents or for use in intravenous injections; particles having an average size of from about 1-5 μm for use in inhalation therapy; and particles having an average size of from about 10-50 μm for applications where larger particles sizes are necessary (column 3, lines 51-59). In response to applicant's argument that there is no teaching, suggestion, or motivation to combine the references, the examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found **either in the references themselves or in the knowledge generally available to one of ordinary skill in the art.**

See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). Furthermore, the reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. **It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant.** See, e.g., *In re Kahn*, 441 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed.Cir. 2006). The advantages specified by Subramaniam et al. are equally applicable. The use of membranes having the sizes and shape as specified are clearly commonly known in the art as also demonstrated by Subramaniam et al.

Applicants have not demonstrated how their process is patentably distinct from the cited prior arts nor do the claims as currently written distinguish the instant invention over the prior arts. In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 1 and 4 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Jakupovic et al. (US Patent No. 6,221,398) in view of Subramaniam et al. (US Patent No. 6,113,795) and Nocent et al., (*J. Pharm. Sci*, 90, 1620-1627), for the reasons of record and the reasons set forth herein.

Response to arguments

Applicants' arguments filed on 07/06/2010 have been fully considered but they are not persuasive.

Applicants argue that for the reasons stated herein above Jakupovic et al and Subramaniam et al, either alone or in combination, do not render the claimed process obvious, Nocent et al relates to the type of solvent, antisolvent and emulsifier and the concentration of the emulsifier for the production of spherical crystals of salbutamol sulfate (see, abstract). Nocent et al does not does not teach or suggest a continuous

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antisolvent solidification process where a liquid medium comprising at least one dissolved organic or inorganic compound is introduced through a membrane in a membrane module into one or more antisolvents, or vice versa. Accordingly, Nocent et al does not remedy the deficiencies of either Jakupovic et al and/or Subramaniam et al.

This is not found persuasive because applicants' resorted to attacking the references individually while the rejection is based on the combined teachings of Jakupovic et al., Subramaniam et al., and Nocent et al. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). For Nocent et al. to be a proper prior art they do not have to teach the continuous process as this limitation is clearly addressed by the *prima facie* argument set forth above. Obviousness can be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so *In re Kahn*, 441 F.3d 977, 986, 78 USPQ2d 1329, 1335 (Fed. Cir. 2006). The test for obviousness is what the combined teachings of the references would have suggested to one of ordinary skill in the art, and all teachings in the prior art must be considered to the extent that they are in analogous arts. In the instant case, Nocent et al. is solely incorporated in the rejection to remedy the deficiency of Jakupovic et al. and Subramaniam et al. for not teaching a process of forming an emulsion before solid particles are formed. Nocent et al. cures this deficiency as clearly set forth in the record. An ordinary skilled artisan would have had a reasonable expectation of success upon combination of the prior art teachings, because all

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references teach similar processes of crystallization of chemical compounds using the solvent/antisolvent system. Specifically, Nocent's process utilizing the addition of an emulsifier demonstrated to be useful during the crystallization process to form a stable emulsion form from the unstable quasi-emulsion formed as a result of interactions between drug and solvent being stronger than the interactions between solvent and antisolvent (see page 1621).

Applicants have not demonstrated how their process is patentably distinct from the cited prior arts nor do the claims as currently written distinguish the instant invention over the prior arts. In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 1, 8, and 9 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Jakupovic et al. (US Patent No. 6,221,398) in view of Subramaniam et al. (US Patent No. 6,113,795) and Chen et al. (US Patent No 7,374,779) as evidenced by Nakagawa et al. (Japan J. Pharmacol. 29, 509-514, 1979), for the reasons of record and the reasons set forth herein.

Response to arguments

Applicants' arguments filed 07/06/10 have been fully considered but they are not persuasive.

Applicants argue that Chen et al. does not teach or suggest a continuous antisolvent solidification process where a liquid medium comprising at least one dissolved organic or inorganic compound is introduced through a membrane in a membrane module into one or more antisolvents, or vice versa. Thus, Chen et al. fails to cure the deficiencies of either of Jakupovic et al and Subramaniam et al. Accordingly, either alone or in combination, Chen et al does not render the claimed invention obvious.

The examiner respectfully disagrees with applicants' assertions because applicants' resorted to attacking the references individually while the rejection is based on the combined teachings of Jakupovic et al., Subramaniam et al., and Chen et al. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). For Chen et al. to be a proper prior art they do not have to teach the continuous process as this limitation is clearly addressed by the prima facie argument set forth above. Obviousness can be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so In *re Kahn*, 441 F.3d 977, 986, 78 USPQ2d 1329, 1335 (Fed. Cir. 2006). The test for obviousness is what the combined teachings of the references would have suggested to one of ordinary skill in the art, and all teachings in the prior art must be considered to the

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extent that they are in analogous arts. In the instant case, Chen et al. is solely incorporated in the rejection to remedy the deficiency of Jakupovic et al. and Subramaniam et al. for not teaching a process of forming **progesterone** or **3-ketodesogestrel** crystal particles. Chen et al. teach a novel pharmaceutical formulation that provides for increased absorption and bioavailability of active agents, particularly active agents that are administered orally (column 8, lines 58-61). Chen et al. teach a list of active agents that includes preferred sex hormones such as progestins, such as, **3-ketodesogestrel** (column 10, line 24). Chen et al. teach that the active agent can be dissolved in appropriate solvent and subjected to crystallization (column 54, lines 35-37 and claim 8) via precipitation by antisolvent (column 54, lines 50-54). Chen et al. teach an illustrative example of a pharmaceutical formulation comprising **progesterone** (column 73, example 48). Nakagawa et al. is solely incorporated as an evidentiary reference to substantiate the fact that progesterone is anti-inflammatory agent.

Applicants have not demonstrated how their process is patentably distinct from the cited prior arts nor do the claims as currently written distinguish the instant invention over the prior arts. In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 1, 11, and 12 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Jakupovic et al. (US Patent No. 6,221,398) in view of Subramaniam et al. (US Patent No. 6,113,795) and Maruyama et al. (US Patent No 5,512,092), for the reasons of record and the reasons set forth herein.

Response to arguments

Applicants' arguments filed 07/06/10 have been fully considered but they are not persuasive.

Applicants argue that Maruyama et al does not teach or suggest a continuous antisolvent solidification process where a liquid medium comprising at least one dissolved organic or inorganic compound is introduced through a membrane in a membrane module into one or more antisolvents, or vice versa, Thus the teachings in Maruyama fail to cure the deficiency in the teachings of Jakupovic as described above.

This is not found persuasive because applicants' resorted to attacking the references individually while the rejection is based on the combined teachings of Jakupovic et al., Subramaniam et al., and Maruyama et al. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). For Maruyama et al. to be a proper prior art they do not have to teach the continuous process as this limitation is clearly addressed by the prima facie argument set forth above. Obviousness can be established by combining or modifying the teachings of the prior art to produce the claimed invention

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where there is some teaching, suggestion, or motivation to do so In re Kahn, 441 F.3d 977, 986, 78 USPQ2d 1329, 1335 (Fed. Cir. 2006). The test for obviousness is what the combined teachings of the references would have suggested to one of ordinary skill in the art, and all teachings in the prior art must be considered to the extent that they are in analogous arts. In the instant case, Maruyama et al. is solely incorporated in the rejection to remedy the deficiency of Jakupovic et al. and Subramaniam et al. for not teaching a process of coating the solid particles, which are formed via the above discussed process, by passing a liquid medium comprising dissolved coating material through a membrane into a suspension of particles. Maruyama et al. teach a method for preparing an aqueous emulsion for coating solid pharmaceutical preparations comprising the steps of dissolving a cellulosic polymer in a mixed solvent of water and an organic solvent capable of being admixed with water in any rate to give a polymer solution, self-emulsifying the polymer solution by mixing with water and then concentrating the resulting emulsified stock solution. The concentration is carried out by removing a part of the liquid components while passing it through a membrane for ultrafiltration until the polymer concentration of the resulting emulsion reaches a level of not less than 7% by weight (see Abstract). Maruyama et al. teach the coating treatment is performed by spraying to the solid particles (column 4, line 21).

Applicants have not demonstrated how their process is patentably distinct from the cited prior arts nor do the claims as currently written distinguish the instant invention over the prior arts. In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references,

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it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 1, 18, and 19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Jakupovic et al. (US Patent No. 6,221,398) in view of Subramaniam et al. (US Patent No. 6,113,795) and Saim et al. (US Patent No 6,858,166), for the reasons of record and the reasons set forth herein.

Response to arguments

Applicants' arguments filed 07/06/10 have been fully considered but they are not persuasive.

Applicants argue that Saim et al does not teach or suggest a continuous antisolvent solidification process where a liquid medium comprising at least one dissolved organic or inorganic compound is introduced through a membrane in a membrane module into one or more antisolvents, or vice versa, Thus the teachings in Saim fail to cure the deficiency in the teachings of Jakupovic as described above.

This is not found persuasive because applicants' resorted to attacking the references individually while the rejection is based on the combined teachings of Jakupovic et al., Subramaniam et al., and Saim et al. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references.

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See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). For *Saim et al.* to be a proper prior art they do not have to teach the continuous process as this limitation is clearly addressed by the *prima facie* argument set forth above. Obviousness can be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so *In re Kahn*, 441 F.3d 977, 986, 78 USPQ2d 1329, 1335 (Fed. Cir. 2006). The test for obviousness is what the combined teachings of the references would have suggested to one of ordinary skill in the art, and all teachings in the prior art must be considered to the extent that they are in analogous arts. In the instant case, *Saim et al.* is solely incorporated in the rejection to remedy the deficiency of *Jakupovic et al.* and *Subramaniam et al.* for not teaching a the dosage in the form of a tablet. *Saim et al.* teach a method for solute particle precipitation, retention and dispersion in a carrier material by taking advantage of the unique properties of pressurized gaseous (e.g. supercritical) fluids to precipitate solute particles from solution and by effectively retaining and dispersing the precipitated particles in a carrier material having good flow and handling properties (column 5, lines 51-58). *Saim et al.* teach that the blends, granulations and partially or fully coated carrier materials, or mixtures thereof, produced by the methods are particularly suited for pharmaceutical processing into **various pharmaceutical formulations and dosage forms, such as tablets and capsules** (column 6, lines 42-46).

Applicants have not demonstrated how their process is patentably distinct from the cited prior arts nor do the claims as currently written distinguish the instant invention

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over the prior arts. In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

This office action is FINAL.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne P. Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu Kassa

8/13/10

/Cherie M. Woodward/
Primary Examiner, Art Unit 1647